IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MARY DICKSON,
Personal Representative of the
Estate of VADA MAE SMITH, *deceased,*

Plaintiff,

v. CIVIL ACTION NO. 2:15-cv-02800

ETHICON INC., ET AL.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the court is a Motion for Summary Judgment [ECF No. 75] filed by the defendants, Ethicon Inc. and Johnson & Johnson. On December 17, 2019, with leave of court, the plaintiff, Mary Dickson, amended her complaint. [ECF No. 85]. On January 13, 2020, the defendants filed a Supplemental Motion for Summary Judgment [ECF No. 90], which incorporates their prior Motion for Summary Judgment [ECF No. 75]. The plaintiff has responded, and both the Motion for Summary Judgment [ECF No. 75] and the Supplemental Motion for Summary Judgment [ECF No. 90] are ripe for adjudication. For the sake of clarity, I **FIND** that the Supplemental Motion for Summary Judgment [ECF No. 90] moots the Motion for Summary Judgment [ECF No. 75]. I therefore **DENY** the defendants' Motion for Summary Judgment [ECF No. 75] as moot. And I **GRANT in part and DENY in part** the defendants' Supplemental Motion for Summary Judgment [ECF No. 90] for the reasons that follow.

I. Background

In this case, the plaintiff is the daughter and personal representative of the estate of Vada Mae Smith, who was implanted with TVT for the treatment of stress urinary incontinence on August 17, 2001. Am. Short Form Compl. [ECF No. 12] ¶¶ 9, 10. Ms. Smith filed suit against the defendants in 2015. She subsequently passed away on September 13, 2016. On August 8, 2017, this court entered an Order identifying Ms. Dickson as the Personal Representative of the Estate of Vada Mae Smith, and granting Ms. Dickson's motion to substitute for Ms. Smith as the plaintiff in this case. This case resides in MDL No. 2327, one of the seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI").

The plaintiff has been proceeding in this matter *pro se* since April of 2018. I recognize the difficulty of navigating multi-district litigation regarding products liability *pro se*. But *pro se* plaintiffs must still observe scheduling orders and rules for discovery, as well as provide sufficient evidence for their claims. This court specifically cautioned Ms. Dickson about proceeding *pro se*, stating that the court, "expects *pro se* litigants to comply with the same time requirements, scheduling orders, and other procedural rules required by counsel of record to observe, including the Local Rules, the Federal Rules of Civil Procedure, and each of the Pretrial Orders entered in this case" and that "failure to comply with all court orders and deadlines may result in the imposition of monetary sanctions, as well as the dismissal of… [her] case with prejudice." [ECF No. 52].

Moreover, this court has afforded the plaintiff considerable flexibility throughout this litigation. On October 6, 2017, the plaintiff filed a Statement of Intent to Proceed Without Counsel. [ECF No. 27]. On October 12, 2018, this court entered an order staying the case until December

11, 2017 to afford the plaintiff an opportunity to obtain new counsel or provide the court with certain information regarding her mother's estate. [ECF No. 30]. This court subsequently entered two additional stay orders to afford the plaintiff more time to retain counsel or provide the requested estate information. [ECF No. 43] (Feb. 12, 2018); [ECF No. 47] (Mar. 22, 2018). The court also granted leave for the plaintiff to amend her complaint after the scheduling order had been entered.

The plaintiff alleged the following claims against the defendants in her Amended Short Form Complaint: negligence (Count I); strict liability – manufacturing defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII). [1] Am. Short Form Compl. [ECF No. 12] ¶13. On December 17, 2019, the plaintiff filed a Second Amended Short Form Complaint, adding two new counts: (a) "illegal, adulterated, and misbranded device;" and (b) wrongful death. Second Am. Short Form Compl. [ECF No. 85].

I find it necessary to address certain issues with the Second Amended Short Form Complaint here. On March 10, 2015, the plaintiff filed a Short Form Complaint, which included a claim for loss of consortium. Short Form Compl. [ECF No. 1]. On February 22, 2017, the plaintiff filed an Amended Short Form Complaint, which dropped Count XVI for loss of consortium. Am.

[1] The defendants do not move for summary judgment on punitive damages (Count XVII) or discovery rule and tolling (Count XVIII) because neither counts are a separate cause of action.

Short Form Compl. [ECF No. 12]. On December 17, 2019, the plaintiff filed a Second Amended Short Form Complaint, which again added Count XVI for loss of consortium. Second Am. Short Form Compl. [ECF No. 85]. It is clearly apparent from the filings and exhibits in this matter that the addition of Count XVI for loss of consortium in the Second Amended Short Form Complaint was inadvertent and improperly alleged. The court therefore **DISMISSES** Count XVI for loss of consortium without prejudice.

Additionally, in both her Short Form Complaint and Amended Short Form Complaint, the plaintiff alleged that Ms. Smith was implanted with a TVT device on August 17, 2001, in Virginia. [ECF Nos. 1, 12]. In her Second Amended Short Form Complaint, the plaintiff alleges, for the first time, that Ms. Smith was implanted with both a TVT device and a TVT-Obturator device ("TVT-O"). [ECF No. 85]. The plaintiff alleges that the TVT-O device was implanted on September 27, 2006, at Greenbrier Valley Medical Center, Lewisburg, WV. On December 11, 2019, this court entered an order [ECF No. 84] granting the plaintiff leave to amend her complaint in response to her request "to add 'wrongful death' to Plaintiffs current charges in this Case." *See* Pl.'s Mot. to Amend Compl. [ECF No. 69]. Given the limited purpose of the leave to amend and the advanced stage of litigation of the case, I **FIND** that the new allegations regarding TVT-O apply only to the two new counts: (a) "illegal, adulterated, and misbranded device;" and (b) wrongful death.

On January 13, 2020, the defendants filed a Supplemental Motion for Summary Judgment on the newly added claims in the Second Amended Complaint. [ECF No. 90]. On January 26, 2020, the plaintiff responded to the Supplemental Motion, attaching the affidavit of Dr. George Nichols. [ECF No. 92]. The defendants subsequently, on February 3, 2020, filed a Motion to Strike the Affidavit by Dr. George Nichols or in the Alternative Motion for Modification of the Scheduling Order. [ECF No. 93]. With entering this Memorandum Opinion and Order, this court

also entered a separate Order denying the Motion to Strike and the Alternative Motion for Modification of the Scheduling Order. Because discovery is not complete on the new claims added in the Second Amended Complaint, this court construes the defendant's Motion as a Motion to Dismiss as to the plaintiff's claim for "illegal, adulterated, and misbranded device."

II. Legal Standard

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby*, Inc., 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

The nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict" in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Dismissal for Failure to State a Claim

Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "When ruling on a motion to dismiss, courts must accept as true all of the factual allegations contained in the Complaint and draw all reasonable inferences in favor of the plaintiff." *Farnsworth v. Loved Ones in Home Care, LLC*, No. 2:18-CV-01334, 2019 WL 956806, at *1 (S.D.W. Va. Feb. 27, 2019) (citing *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 440 (4th Cir. 2011)).

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the plaintiff's factual allegations, taken as true, must "state a claim to relief that is plausible on its face." *Robertson v. Sea Pines Real Estate Co.*, 679 F.3d 278, 288 (4th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). The plausibility standard is not a probability requirement, but "asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). Although "the Complaint must contain sufficient facts to state a claim that is plausible on its face, it nevertheless need only give the defendant fair notice of what the claim is and the grounds on which it rests." *Hall v. DIRECTV, LLC*, 846 F.3d 757, 777 (4th Cir. 2017). Thus, "a Complaint is to be construed liberally so as to do substantial justice." *Id.*

C. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they

not been transferred for consolidation." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir.1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir.1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir.1981); *Carlson v. Bos. Sci. Corp.*, No. 2:13-CV-05475, 2015 WL 1956354, at *2 (S.D.W. Va. Apr. 29, 2015). *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08–md–01968, 2010 WL 2102330, at *7 (S.D.W.Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, which is the case here, I consult the choice-of-law rules of the state in which the implantation surgery took place. *See Sanchez v. Boston Scientific Corp.*, 2:12–cv–05762, 2014 WL 202787, at *4 (S.D.W.Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). In this case, Ms. Smith received the implantation surgery in Virginia. Thus, the choice-of-law principles of Virginia guide this court's choice-of-law analysis.

Virginia's choice-of-law principles dictate that courts must apply the substantive law of the state where the alleged wrong occurred. *Kraft Foods N. Am., Inc. v. Banner Eng'g & Sales, Inc.*, 446 F. Supp. 2d 551, 566 (E.D. Va. 2006). Under this rule, courts select "the law of the place where the wrongful act occurred, even when that place differs from the place where the effects of injury are felt." *Milton v. IIT Research Institute*, 138 F.3d 519, 522 (4th Cir. 1998); *see also Diaz*

Vicente v. Obenauer, 736 F. Supp. 679, 690 (E.D. Va. 1990) (holding that Virginia law applied because the "tortious conduct—the legal injury—occurred" in Virginia, even though the plaintiffs suffered the economic effects of the tort in Mexico). Here, Ms. Smith underwent implantation of TVT in Virginia. Am. Short Form Compl. [ECF No. 12] ¶ 11. It is immaterial under the choice of law standards that Ms. Smith was a West Virginia resident and received subsequent medical care and treatment in West Virginia. *See* Dep. of Mary Dickson [ECF No. 75–1] 34–37. She may have felt the effects of the implantation of TVT in West Virginia, but Virginia is the place where the alleged wrongful act—the implantation—occurred. Therefore, I apply substantive law of Virginia.

D. Federal Rules of Civil Procedure Rule 26

Federal Rule of Civil Procedure 26(a)(2) governs the discovery disclosure rules for expert witnesses. The Rule requires parties to disclose "to the other parties the identity of any [expert] witness it may use at trial to present evidence." Fed. R. Civ. P. 26(a)(2). "Unless otherwise stipulated or ordered by the court, this disclosure must be accompanied by a written report—prepared and signed by the witness—if the witness is one retained or specially employed to provide expert testimony in the case…." *Id.* The report must contain the following:

> (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years; (v) a list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial or by deposition; and (vi) a statement of the compensation to be paid for the study and testimony in the case.

Id. If a party fails to obey a court order to provide discovery then the court may issue further just orders—such as, dismissing the action or proceedings in whole or in part. Fed. R. Civ. P. 37(b)(2).

III. Analysis

A. Strict Liability Claims – Counts II–V

I find that Counts II through V of the plaintiff's complaint are not cognizable under Virginia law. Virginia does not recognize strict liability claims for products liability torts. *Evans v. Nacco Materials Handling Grp., Inc.*, 810 S.E.2d 462, 469 (Va. 2018); *Sensenbrenner v. Rust, Orling & Neale, Architects, Inc.*, 374 S.E.2d 55, 57, n.4 (Va. 1988) ("Virginia law has not adopted § 402A of the Restatement (Second) of Torts and does not permit tort recovery on a strict-liability theory in products-liability cases."). Under Virginia law, "when alleging that a product suffered from a design defect, a plaintiff may proceed under a theory of implied warranty of merchantability or under a theory of negligence." *Evans*, 810 S.E.2d at 469. Additionally, Virginia does not recognize a tort for failure to warn based on strict liability. *Petruska v. Cutech, Inc.*, No. 12617 1991 WL 835316, at *1 (Va. Cir. Ct. Nov. 21, 1991). The following claims brought by the plaintiff are products liability torts based on a theory of strict liability: manufacturing defect (Count II); failure to warn (Count III); defective product (Count IV); design defect (Count V). *See* Am. Short Form Compl. [ECF No. 12] ¶13. I therefore **GRANT** the defendants' Supplemental Motion for Summary Judgment on Counts II, III, IV, and V.

B. Consumer Protection Claims – Count XIII

I find that Count XIII is not cognizable under Virginia consumer protection laws. The plaintiff asserts a claim for violation of state consumer protection laws (Count XIII). Am. Short Form Compl. [ECF No. 12] ¶13. Although somewhat unclear from the plaintiff's Complaint, I presume this claim is brought pursuant to the Virginia Consumer Protection Act ("VCPA"), Va. Code §§ 59.01–196–207. That statute, by its own terms, does not apply to federally regulated products. Va. Code § 59.1–199(A); *see also Ball v. Takeda Pharm. Am., Inc.*, 963 F. Supp. 2d 497,

507 (E.D. Va. 2013) (holding that VCPA did not apply to the plaintiff's claim that a drug's warning label violated consumer protection laws because the drug-at-issue was regulated by the FDA); *Ali v. Allergan USA, Inc.*, No. 1:12–CV–115, 2012 WL 3692396, at *19 (E.D.Va. Aug. 23, 2012) (granting motion to dismiss VCPA claim against medical device manufacturer because "[r]epresentations about the LAP–BAND in marketing materials for the device are authorized and regulated by the FDA under federal law"). In this case, TVT is an FDA-approved medical device approved through the 510k clearance process, whose warnings and labels were regulated by the FDA in accordance with federal law. Therefore, VCPA does not apply to the product-at-issue. The defendants' Supplemental Motion for Summary Judgment on Count XIII claiming a violation of state consumer protection laws is thus **GRANTED**.

C. Fraud and Negligent Misrepresentation – Counts VI–IX

The plaintiff asserts three claims based on fraud: common law fraud (Count VI); fraudulent concealment (Count VII); and constructive fraud (Count VIII). The defendants argue that under Virginia law, the plaintiff's fraud claims cannot survive summary judgment because they are based on alleged misrepresentations made not directly to Ms. Smith, but rather to her through a third-party, her implanting physician. *See* Def.'s Mem. in Supp. of Summ. J. [ECF No. 76] 18.

This court previously addressed this issue regarding fraud, fraudulent concealment, and constructive fraud in another MDL case. *See Scholl v. Ethicon, Inc.*, No. 2:12-cv-007398, 2016 WL 7242552, at *4 (S.D. W. Va. Dec. 14, 2016). In *Scholl*, this court held the following,

> Virginia law requires proof of reliance by the injured party, as opposed to reliance by a third party, in order to maintain an action for fraud. *Rich. Metro. Auth. v. McDevitt St. Bovis, Inc.*, 507 S.E.2d 344, 346 (Va. 1998) (noting that fraud claims require "reliance by the party misled"). Establishing the element of reliance by the injured party can be "problematic" in the medical device context because any alleged misrepresentations are typically made to the prescribing doctor or other learned intermediary. Robert E. Draim,

> Va. Prac. Series Prods. Liab. § 6:7. Mrs. Scholl never interacted with any representative of Ethicon, nor did she read or review any materials created by Ethicon. The court has not found any evidence that Mrs. Scholl "relied" on a misrepresentation by Ethicon, so this element cannot be met and must be dismissed as a matter of law.

Id. The facts in this case are similar to those in *Scholl*. The plaintiff has not offered even a scintilla of evidence that Ms. Smith relied on misrepresentation made to her *directly* from the defendants. In her deposition, Ms. Dickson testified that she was present during Ms. Smith's pre-operative visit with the physician. Mary Dickson Dep. Tr. 29:3–20 [ECF 75–1] Ex. C. Ms. Dickson further testified that to her knowledge, her mother never saw any brochures, documents, or pamphlets from Ethicon or Johnson & Johnson. *Id.* at 25:9–11; 26:1–5; 29:20–22. The plaintiff has not presented any evidence that Ms. Smith ever interacted with any representative of the defendants. Merely showing that Ms. Smith's physician relied on the defendants' alleged misrepresentations cannot establish the essential element of reliance for fraud, fraudulent concealment, and constructive fraud. Therefore, there is not a dispute of material fact in this case that would allow the plaintiff to recover on her fraud-based claims. Thus, the court **GRANTS** the defendants' Supplemental Motion for Summary Judgment on Counts VI, VII, and VIII.

Furthermore, in Virginia negligent misrepresentation is not a separate cause of action from constructive fraud. *Baker v. Elam*, 883 F. Supp. 2d 576, 581 (E.D. Va. 2012). "[T]he essence of constructive fraud is negligent misrepresentation." *Id.* (quoting *Richmond Metropolitan Auth. v. McDevitt Street Bovis, Inc.*, 507 S.E.2d 344, 347 (Va. 1998)). A plaintiff's inability to establish constructive fraud thus precludes her from recovering for negligent misrepresentation. As previously explained, the plaintiff here cannot as a matter of law prove reliance on the defendants' misrepresentation—an essential element of constructive fraud—ergo Ms. Dickson cannot demonstrate a negligent misrepresentation claim under Virginia law. Thus, the court **GRANTS** the defendants' Supplemental Motion for Summary Judgment on Count IX.

D. Medical Causation Expert – Counts I, X, XI, XII, XIV, XV

The defendants' Supplemental Motion for Summary Judgment regarding the plaintiff's remaining tort and contract claims—negligence (Count I); negligent infliction of emotional distress (Count X); breach of expressed warranty (Count XI); breach of implied warrant (Count XII); gross negligence (Count XIV), and unjust enrichment (Count XV)— turns on the issue of causation. Def.'s Mem. in Supp. of Mot. for Summ. J. [ECF No. 76] 7. "Under any theory of tortious injury, one requisite element of a claim is a causal connection between defendant's conduct and a plaintiff's injury." *Hartwell v. Danek Medical, Inc.*, 47 F. Supp. 2d 703, 707 (W.D. Va. 1999). It is undisputed that Ms. Dickson refused to produce an expert up until January 26, 2020 when she filed an affidavit by Dr. George Nichols. *See* Pl.'s Correspondence to Court [ECF No. 69]; Affidavit by Dr. George Nichols [ECF No. 92]. The defendants argue that because the plaintiff has not timely or properly produced a competent expert opinion that links TVT to Ms. Smith's alleged injuries and death, the plaintiff has failed to offer even a scintilla of evidence of causation. *Id.* And thus, according to the defendants, awarding summary judgment on the plaintiff's negligence, warranty, and unjust enrichment claims is appropriate. I agree.

Under Virginia law, "[p]roof of legal causation in a medical device case must be by expert testimony and the expert's opinion must be stated in terms of reasonable probability." *Hartwell v. Danek Med., Inc.*, 47 F. Supp. 2d 703, 707–08 (W.D. Va. 1999); *Rohrbough v. Wyeth Laboratories, Inc.*, 916 F.2d 970, 972 (4th Cir.1990). Cases that involve issues that are medically complex and outside common knowledge and lay experience require expert testimony to assist the fact finder. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 645–46 (4th Cir. 2018). In *In re Lipitor*, the court distinguished injuries whose proximate cause was within common knowledge—such as a "gunshot wound to

the head of an otherwise healthy person who died shortly thereafter"—from injuries that required an expert to determine proximate cause—such as diabetes. *Id.*

In this case, the plaintiff has not properly offered a competent expert opinion regarding causation, either general or specific, as to TVT. The deadline for the plaintiff to disclose testifying expert witnesses was August 28, 2018, and thus has long since passed. [ECF No. 55]. Rule 26 requires "a party [to] make these disclosures at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(2)(D). "[A] scheduling order under Rule 16(b) is not a frivolous piece of paper, idly entered, which can be cavalierly disregarded by counsel without peril. . . . Indeed, a scheduling order is the critical path chosen by the trial judge and the parties to fulfill the mandate of Rule 1 in 'securing the just, speedy, and inexpensive determination of every action.'" *Price v. Marsh*, No. 2:12-cv-05442, 2013 WL 5409811, at *2 (S.D. W. Va. Sept. 25, 2013) (Goodwin, J.) (internal citation omitted) (quoting *Marcum v. Zimmer*, 163 F.R.D. 250, 253 (S.D. W. Va. 1995)).

Under Rule 37(c)(1), "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified." Because "[t]he purpose of Rule 26(a) is to allow litigants 'to adequately prepare their cases for trial and to avoid unfair surprise,' . . . a party who fails to comply with the expert witness disclosure rules is prohibited from 'us[ing] that information or witness to supply evidence . . . at a trial, unless the failure was substantially justified or is harmless.'" *Bresler v. Wilmington Trust Co.*, 855 F.3d 178, 190 (4th Cir. 2017) (quoting *Russell v. Absolute Collection Servs., Inc.*, 763 F.3d 385, 396 (4th Cir. 2014); Fed. R. Civ. P. 37(c)(1)). Thus, "[t]he Rule 37(c) advisory committee notes emphasize that the 'automatic sanction' of exclusion 'provides a strong inducement for disclosure of material that the disclosing party would expect to use as evidence." *Southern States Rack &*

Fixture, Inc. v. Sherwin-Williams Co., 318 F.3d 592, 595 n.2 (4th Cir. 2003) (quoting Fed. R. Civ. P. 37(c) adv. committee note (1993)).

Prior to filing an affidavit on January 26, 2020, the plaintiff had made it clear that she did not plan on "using expert witnesses" to prove her case. Pl.'s Correspondence to Court [ECF No. 69] ("I will not be deposing witnesses, or using expert witnesses, due to no money to pay them."). I recognize the difficulty of navigating multidistrict litigation regarding products liability *pro se*. But *pro se* plaintiffs must still provide sufficient evidence for their claims in a timely manner that complies with discovery deadlines. I further note that it would be highly prejudicial to the defendants to allow the affidavit of Dr. Nichols to apply to the claims alleged in the Amended Short Form Complaint, when up until January 26, 2020 the defendants had operated under the reasonable assumption that Ms. Dickson did not intend to use an expert witness. I therefore exclude any consideration of Dr. Nichols' Affidavit in evaluating Counts I, X, XI, XII, XIV, XV.

Causation between the TVT and Ms. Smith's death and injuries is an essential element of each of the plaintiff's negligence, warranty, and unjust enrichment claims. The plaintiff must demonstrate that TVT implanted in Ms. Smith was defective and that that defect caused her injuries. Both arguments require specialized knowledge and expertise. The absence of qualified expert testimony in this case would allow the fact finder to engage in impermissible post hoc reasoning—the plaintiff did not suffer injuries; the plaintiff received the implant of TVT; the plaintiff then began to suffer injuries and subsequently died ergo TVT's faulty design, manufacturing, warnings, or implantation caused the injuries. *See McCauley v. Purdue Pharma L.P.*, 331 F. Supp. 2d 449, 464 (W.D. Va. 2004). Although this line of reasoning is tempting to a layperson, it is too superficial. In Virginia, causation of complex medical diagnoses requires more than a mere temporal link between an implant and symptoms. Therefore, the court **GRANTS** the

defendants' Supplemental Motion for Summary Judgment on negligence (Count I), negligent infliction of emotional distress (Count X), breach of expressed warranty (Count XI), breach of implied warranty (Count XII), gross negligence (Count XIV), and unjust enrichment (Count XV).

E. New Claims Alleged in the Second Amended Complaint

The plaintiff added two new counts in her Second Amended Complaint: (a) "illegal, adulterated, and misbranded device" and (b) wrongful death. The prior scheduling order [ECF No. 55] does not apply to these new claims, added on December 17, 2019. The parties have not had the opportunity to engage in proper discovery on these two new claims.

(1) "Illegal, Adulterated and Misbranded Device"

I construe the defendants' Supplemental Motion for Summary Judgment as a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6) with regard to the plaintiff's claim for "illegal, adulterated and misbranded device."

The plaintiff asserts a claim for "Illegal, Adulterated, and Misbranded Device[,]" claiming that the device implanted in Ms. Smith by Dr. Lassere in 2001 was provided to Dr. Lassere before it was cleared by the FDA on October 26, 2001. As far as this court is aware, there is not an independent cause of action or claim for "illegal, adulterated, and misbranded device." I thus construe the claim—as the defendants have—as an attempt by the plaintiff to assert a claim for violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 331(b), which prohibits the "adulteration or misbranding of any . . . device . . . in interstate commerce."

The Supreme Court has expressly held: "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions" of the FDCA. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349, n. 4 (2001). Federal courts have consistently held that private citizens cannot assert

claims for violation of the FDCA. *See*, *e.g.*, *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d. 1114, 1126 (D. Or. 2012) (holding that "failure to comply with the FDCA cannot form the basis for a state-law claim" and, therefore, "Plaintiffs cannot sue to enforce the federal statute."); *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33, 35 (M.D. Pa. 1989) ("The FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act."); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (holding that plaintiff was "not empowered to enforce independently the FDCA").

The plaintiff, therefore, has not alleged a plausible claim upon which relief can be granted. The defendants' Motion is **GRANTED** pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure on the plaintiff's allegations of "Illegal, Adulterated and Misbranded Device" and the claim is **DISMISSED with prejudice**.

(2) Wrongful Death

The defendants requested summary judgment on the plaintiff's wrongful death claim based on her lack of an expert witness. As previously discussed, the defendants filed a Motion to Strike the Affidavit of Dr. Nichols or in the Alternative Motion for Modification of the Scheduling Order. [ECF No. 93]. Simultaneous with this Memorandum Opinion and Order, I entered a separate Order denying the defendants' Motion to Strike and their Alternative Motion for a Modification of the Scheduling Order. Because I did not strike the affidavit and the court intends to issue a new scheduling order for the wrongful death claim, I find the defendants' Motion for Summary Judgment premature. Therefore, I **DENY** the Motion as to the wrongful death claim.

IV. Conclusion

The defendants' Motion for Summary Judgment [ECF No. 75] is **DENIED as moot**. The defendants' Supplemental Motion for Summary Judgment [ECF No. 90] is **GRANTED** on the

following claims: negligence (Count I); strict liability – manufacturing defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); and unjust enrichment (Count XV). The defendants' Motion [ECF No. 90], construed as a motion to dismiss, is **GRANTED** as to the plaintiff's claim for "illegal, adulterated and misbranded device." The defendants' Motion [ECF No. 90] is **DENIED** as to the plaintiff's claim for wrongful death. The plaintiff's newly alleged claim for loss of consortium is **DISMISSED** without prejudice. I **FIND** that the new allegations regarding TVT-O apply only to the remaining new count: (a) wrongful death.

The Clerk is directed to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: March 27, 2020

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE